

## **REMARKS/ARGUMENTS**

Reexamination and reconsideration of this Application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above claim amendments and remarks that follow.

Claims 7, 12, and 25 have been canceled without prejudice. New claims 28-30 have been added and find support in originally filed claim 19, as well as pages 7 and 16 of the originally filed application. Claims 1, 2, 4-6, 13-15, 17-19, 21, 23, 24, and 27-30 are pending.

### Rejections under 35 U.S.C. §103(a)

Claims 1, 2, 4, and 5 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 6,331,116 to Kaufman et al. in view of U.S. Patent No. 5,352,434 to Illig et al. Claim 6 stands rejected under the same section as allegedly being obvious over Kaufman et al. in view of Illig et al. and Bircher et al. Applicant respectfully traverses these rejections.

Applicant respectfully submits the Examiner has taken a position on the teaching of Illig et al. that is based on multiple conflicting arguments. First, the Examiner argues that Illig et al. teach that barium dosage should be kept as low as is consistent with achieving contrast enhanced imaging. Second, the Examiner argues that since the primary reference, Kaufman et al., teaches a dosage volume of 250 mL, the presently claimed volume of at least about 20 mL can be considered to be a low volume. Third, the Examiner argues the differences in volumes and concentrations between Kaufman et al. and Illig et al. are inconsequential. Applicant submits the Examiner has failed to give proper recognition to the different uses of the Kaufman et al. formulations and the Illig et al. formulations and has thus failed to recognize that a skilled person would not combine these two documents and arrive at the present invention.

The purpose of the Illig et al. formulations is for coating the GI tract. The purpose of the Kaufman et al. formulations is to enhance the images of any stool remaining in the colon. These are two distinct purposes, and a skilled person would recognize that the formulations used for the two distinct purposes would require very different specifications.

Kaufman teaches ingesting a total dose of 750 cc of 2.1% w/v barium suspension – i.e., a large total dose to achieve the more rigorous task of enhancing stool imaging. In contrast, as the Examiner pointed out, Illig et al. teaches keeping total dosage of contrast agent low. Coating the walls of the GI tract is a very different endeavor, one which Illig et al. accomplish by combining the contrast agent with a polymeric material. Thus, Illig et al. provide a vehicle whereby a low dose of contrast agent can achieve the required coating purpose.

The Examiner also appears to intermingle contrast agent dose with formulation volume. These are two distinct terms. Illig et al. teaches using a low dose of contrast agent. This is completely independent of formulation volume. Illig et al. could teach delivering the contrast agent in a formulation at a volume of 1 liter or 10 milliliters, the contrast agent concentration could simply be adjusted to keep the total contrast agent dosage low. The Examiner desires to separate the overall teaching of Illig et al. (i.e., “low dosage”) from the specific examples of Illig et al. This is simply not possible, however, when the Examiner is arguing a skilled person would combine the “low dosage” teaching of Illig et al. with the high dosage teaching of Kaufman et al. Illig et al. describe their formulation in terms of contrast agent concentration. To determine what a “low dosage” really is according to Illig et al. it is necessary to consider the specific examples. A skilled person viewing Kaufman et al. and Illig et al. would recognize that they teach very different formulations used for different purposes and would not seek to combine them. Even if the documents are combined, they still do not teach how to arrive at the present invention. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejections.

Claims 7, 12, and 25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,782,762 to Vining et al. in view of the Children’s Hospital at Westmead (CHW) Fact Sheet, and further in view of Bircher et al. Claims 7, 12, and 25 have been canceled. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 13-15 and 18 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al., “MR Colonography Without Colonic Cleansing: A New Strategy to Improve Patient Acceptance”, (2001), *AJR* 177: 823-827 (hereinafter referred to

as “Lauenstein et al. *AJR* 177”) in view of Callstrom et al., “CT Colonography without Cathartic Preparation: Feasibility Study”, (2001), *Radiology*, 219:693-698 and Illig et al. Claim 17 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al. *AJR* 177, Callstrom et al., Kaufman et al., and Illig et al. Applicant respectfully traverses these rejections.

Applicant has already discussed above the failures of the Examiner’s allegations in relation to combining Illig et al. with Kaufman et al. Applicant submits said discussion likewise applies to the present rejections where Illig et al. is combined with Lauenstein et al. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections.

Claims 19-21, 23, and 24 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al., “MR Colonography with Barium-based Fecal Tagging: Initial Clinical Experience”, *Radiology*, 223(1):248-254 (hereinafter “Lauenstein et al., *Radiology* 223”). Claim 26 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al., *Radiology* 223 in view of Bircher et al. Claim 27 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lauenstein et al., *Radiology* 223 in view of Callstrom et al. Applicant respectfully traverses this rejection.

Applicant submits that Lauenstein et al., *Radiology* 223 is not properly cited prior art as the subject matter of the presently rejected claims was conceived and reduced to practice prior to the publication date of Lauenstein et al., *Radiology* 223. In support of this statement, Applicant has provided herewith a Declaration under 37 CFR 1.131 showing prior invention. Applicant also submits that the date of invention of the subject matter of new claims 28-30 likewise predates Lauenstein et al., *Radiology* 223.

Applicant respectfully submits that all claims, as now submitted, are in condition for immediate allowance. Accordingly, a Notice of Allowance is respectfully requested in due course. If any minor formalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow

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consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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